DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 11, 2016

BD Biosciences
% Ms. Elizabeth Landon
Staff Regulatory Affairs Specialist
2350 Qume Drive
San Jose, California 95131

Re: K141468
Trade/Device Name: BD FACSCanto flow cytometer (4-3-3 configuration) with BD FACSCanto clinical software and BD FACSDiva software and BD FACSCanto II flow cytometers (4-2-2 and 5-3 configurations) with BD FACSCanto clinical software and BD FACSDiva software
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: OYE
Dated: January 26, 2015
Received: January 27, 2015

Dear Ms. Landon:

This letter corrects our substantially equivalent letter of February 27, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809**]**); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809**]**), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, ″Misbranding by reference to premarket notification″ (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kelly Oliner -S

FOR
Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141468

Device Name

BD FACSCanto™ flow cytometer (4-3-3 configuration) with BD FACSCanto™ clinical software and BD FACSDiva™ software

Indications for Use *(Describe)*

The BD FACSCanto flow cytometer (4-3-3 configuration) functions as part of a system with dedicated clinical software intended for use with cleared or approved in vitro diagnostic (IVD) assays that are indicated for use with the instrument for the identification and enumeration of human cell subsets. Only six detection channels using a blue (488 nm) and a red (640 nm) laser have been cleared for in vitro diagnostic use. For use with or without the BD FACS Sample Prep Assistant III.

For in vitro diagnostic use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141468

Device Name

BD FACSCanto™ II flow cytometers (4-2-2 and 5-3 configurations) with BD FACSCanto™ clinical software and BD FACSDiva™ software

Indications for Use *(Describe)*

The BD FACSCanto II flow cytometers (4-2-2 and 5-3 configurations) function as part of a system with dedicated clinical software intended for use with cleared or approved in vitro diagnostic (IVD) assays that are indicated for use with the instrument for the identification and enumeration of human cell subsets. Only six detection channels using a blue (488 nm) and a red (633 nm) laser have been cleared for in vitro diagnostic use. For use with or without the BD FACS Sample Prep Assistant III.

For in vitro diagnostic use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Date of Summary: Feb. 26, 2015

5.1 Submitted By

BD Biosciences
2350 Qume Drive
San Jose, CA 95131-1807 USA

Contact: Elizabeth Landon, Staff Regulatory Affairs Specialist
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5.2 Trade Name/Device Name:

BD FACSCanto™ flow cytometer (4-3-3 configuration) with BD FACSCanto™ clinical software and BD FACSDiva™ software and

BD FACSCanto™ II flow cytometers (4-2-2 and 5-3 configurations) with BD FACSCanto™ clinical software and BD FACSDiva™ software

Classification: Class II
Classification Name: Automated Differential Cell Counter
Classification Panel: Hematology and Pathology Devices Panel
Classification Code: OYE
Regulation: 21 CFR 864.5220

5.3 Indications for Use

Device Name: BD FACSCanto™ II flow cytometers (4-2-2 and 5-3 configurations) with BD FACSCanto™ clinical software and BD FACSDiva™ software

The BD FACSCanto™ II flow cytometers (4-2-2 and 5-3 configurations) function as part of a system with dedicated clinical software intended for use with cleared or approved in vitro diagnostic (IVD) assays that are indicated for use with the instrument for the identification and enumeration of human cell subsets. Only six detection channels using a blue (488 nm) and a red (633 nm) laser have been cleared for in vitro diagnostic use. For use with or without the BD FACS™ Sample Prep Assistant III.

For in vitro diagnostic use.

Device Name: BD FACSCanto™ flow cytometer (4-3-3 configuration) with BD FACSCanto™ clinical software and BD FACSDiva™ software

The BD FACSCanto™ flow cytometer (4-3-3 configuration) functions as part of a system with dedicated clinical software intended for use with cleared or approved in vitro diagnostic (IVD) assays that are indicated for use with the instrument for the identification and enumeration of human cell subsets. Only six detection channels using a blue (488 nm) and a red (640 nm) laser have been cleared for in vitro diagnostic use. For use with or without the BD FACS™ Sample Prep Assistant III.

For in vitro diagnostic use.

5.4 Basic Description of the Device

The BD FACSCanto and FACSCanto II (BD FACSCanto II 4-2-2, BD FACSCanto II 5-3 and BD FACSCanto 4-3-3 configurations) are comprised of a flow cytometer, a fluidics cart, and a computer workstation. The flow cytometer acquires and analyzes the sample, the fluidics cart contains operational fluids, and the computer displays and prints the analysis. The flow cytometer utilizes three subsystems: fluidics, optics, and electronics. The computer workstation runs two software packages: BD FACSCanto clinical software for automatic immunophenotyping assays prepared using the lyse/wash or lyse/no-wash methods, and BD FACSDiva software for installation, service, and manual user-validated applications. The BD FACSCanto and FACSCanto II systems can optionally be used with the BD FACSLoader for automatic sample introduction, a standalone barcode reader for data input into BD FACSCanto clinical software and BD FACSDiva software, and/or the BD FACS Sample Prep Assistant III for automatic sample preparation of assays utilizing the lyse/no-wash method.

The BD FACSCanto II system is available in three configurations. The base “4-2” configuration model (cleared by K062087) contains two lasers (blue and red) and seven photomultiplier tubes (PMTs); the “5-3” and “4-2-2” configuration models contain the same two lasers (blue and red). The systems have two additional PMTs for a total of nine. Additionally, the 4-2-2 model is also manufactured with a 405-nm violet laser. The 5-3 and 4-2-2 configurations support the detection of additional fluorochromes for research applications. Only six detection channels using the red and blue lasers within these models can be used with IVD assays. The performance between the three configurations in their detection of forward scatter (FSC), side scatter (SSC), and the six common fluorochromes are the same and performance and clinical data show equivalent results for the IVD assays. The only difference is in their capability to detect an additional seventh or eighth fluorescence parameter for research use only applications.

The BD FACSCanto system is available in two configurations. The base “4-2” configuration model (cleared by K040725 and K041074) contains two lasers (blue and red) and seven photomultiplier tubes (PMTs); the “4-3-3” configuration model

contains blue and red lasers as well. The 4-3-3 configuration has four additional PMTs for a total of eleven. Additionally, the 4-3-3 configuration is manufactured with a 405-nm violet laser, which is the same laser used within the BD FACSCanto II family. This violet laser supports the detection of additional fluorochromes for research applications. Only six detection channels using the red and blue lasers within this model can be used with IVD assays. The performance between the two configurations in their detection of forward scatter (FSC), side scatter (SSC), and the six common fluorochromes are the same and performance and clinical data show equivalent results for the IVD assays. The only difference is in their capability is to detect additional fluorescence parameters (up to 10 colors and 12 parameters) for research use only applications.

Table 5-1: Instrument Configurations of BD FACSCanto II

Model	**Lasers**	**Optics and Parameter/Fluorochrome Detection**
BD FACSCanto II 4-2 (reference device)	488-nm (blue) 633-nm (red)	7 photomultiplier tubes Parameter detection: FSC, SSC, six fluorochromes
BD FACSCanto II 5-3	488-nm (blue) 633-nm (red)	9 photomultiplier tubes Parameter detection: FSC, SSC, eight fluorochromes
BD FACSCanto II 4-2-2	405-nm (violet) 488-nm (blue) 633-nm (red)	9 photomultiplier tubes Parameter detection: FSC, SSC, eight fluorochromes

Table 5-2: Instrument Configurations of BD FACSCanto

Model	**Lasers**	**Optics and Parameter/Fluorochrome Detection**
BD FACSCanto 4-2 (predicate device)	488-nm (blue) 633-nm (red)	7 photomultiplier tubes Parameter detection: FSC, SSC, six fluorochromes
BD FACSCanto 4-3-3	405-nm (violet) 488-nm (blue) 640-nm (red)	11 photomultiplier tubes Parameter detection: FSC, SSC, ten fluorochromes

The performance of these configurations in their detection of forward scatter (FSC), side scatter (SSC), and the six common fluorochromes is equivalent to the predicate BD FACSCanto 4-2 configuration. The only difference is in their capability to detect additional fluorescence parameters (for research use only).

The IVD applications/assays remain unchanged and perform equivalently across configurations.

5.5 Predicate Device

BD FACSCanto system (4-2 configuration) with BD FACSCanto clinical software and BD FACSDiva software (premarket notifications K041074 and K040725 respectively).

5.6 Reference Device

BD FACSCanto II system (4-2 configuration) with BD FACSCanto clinical software and BD FACSDiva software (K062087).

5.7 Predicate Device and Reference Device Selection Rationale

The BD FACSCanto 4-2 configuration (cleared with K041074 and K040725) is chosen as predicate since the subsequent configurations were based on the same starting platform and it was representative to all three devices in the submission. Additionally, the BD FACSCanto II 4-2 configuration is used as a reference device since all the changes made in BD FACSCanto II platform, which includes the 5-3 and 4-2-2 configurations, were cleared in K062087.

5.8 Comparison to the Predicate - Similarities and Differences

5.8.1 Intended Use

Intended use statements are noted in Table 5-3 below.

5.8.2 Technological Characteristics

The technological differences between the BD FACSCanto II 5-3, BD FACSCanto II 4-2-2, and BD FACSCanto 4-3-3 configurations and the BD FACSCanto system 4-2 configuration are in the areas of optics and detection capability. The primary changes are additional detectors and a third laser to expand research use parameters.

The performance of the IVD channels, using IVD assays, has been verified to be equivalent between all configurations against the predicate BD FACSCanto system 4-2 configuration.

Table 5-3: Similarities/Differences – Predicate and reference devices (BD FACSCanto 4-2, BD FACSCanto II 4-2) against subject devices (BD FACSCanto II 5-3, BDFACSCanto II 4-2-2 and BD FACSCanto 4-3-3]

Feature/ Attribute	BD FACSCanto (4-2): Predicate Device	BD FACSCanto II (4-2): Reference Device	BD FACSCanto II (5-3)	BD FACSCanto II (4-2-2)	BD FACSCanto (4-3-3)
Intended Use	The BD FACSCanto (4-2) system is intended for use as in vitro diagnostic devices for the identification and enumeration of lymphocyte subsets in human cells in suspension. • Immunophenotyping in clinical laboratories, using previously cleared in vitro diagnostic assays for flow cytometry. • Identification and enumeration of lymphocyte subsets in human cells in suspension. • For in vitro diagnostic use. • For use with or without the BD FACS Sample Prep Assistant II.	The BD FACSCanto II (4-2) system is intended for use as in vitro diagnostic devices for the identification and enumeration of lymphocyte subsets in human cells in suspension. • Immunophenotyping in clinical laboratories, using previously cleared in vitro diagnostic assays for flow cytometry. • Identification and enumeration of lymphocyte subsets in human cells in suspension. • For in vitro diagnostic use. • For use with or without the BD FACS Sample Prep Assistant III	The BD FACSCanto II flow cytometers (4-2-2, and 5-3 configurations) function as part of a system with dedicated clinical software intended for use with cleared or approved in vitro diagnostic (IVD) assays that are indicated for use with the instrument for the identification and enumeration of human cell subsets. Only six detection channels using a blue (488 nm) and a red (633 nm) laser have been cleared for in vitro diagnostic use. For use with or without the BD FACS Sample Prep Assistant III. For in vitro diagnostic use.	Same as BD FACSCanto II (5-3)	The BD FACSCanto flow cytometer (4-3-3 configuration) functions as part of a system with dedicated clinical software intended for use with cleared or approved in vitro diagnostic (IVD) assays that are indicated for use with the instrument for the identification and enumeration of human cell subsets. Only six detection channels using a blue (488 nm) and a red (640 nm) laser have been cleared for in vitro diagnostic use. For use with or without the BD FACS Sample Prep Assistant III. For in vitro diagnostic use.
Device Classification and Product Code	Automated Differential Cell Counter 21 CDR 864.5220 Product Code: OYE	Same	Same	Same	Same

Feature/ Attribute	BD FACSCanto (4-2): Predicate Device	BD FACSCanto II (4-2): Reference Device	BD FACSCanto II (5-3)	BD FACSCanto II (4-2-2)	BD FACSCanto (4-3-3)
IVD Excitation	**Blue laser** 488nm solid state, 20mW **Red laser** 633nm HeNe, 17mW	**Blue laser** Same **Red laser** Same	**Blue laser** Same **Red laser** Same	**Blue laser** Same **Red laser** Same	**Blue laser** Same **Red laser** 640nm solid state, 40mW
IVD Optical Detection	**1st detector array** Blue **"**octagon" receives 488nm-excited and scattered light. The array is configured to detect SSC and 4 fluorochromes (FITC, PE, PerCP/PerCP-Cy5.5, PE-Cy7) **2nd detector array** Red **"**trigon" receives 633nm-excited light. The array is configured to detect 2 fluorochromes (APC, APC-Cy7)	**1st detector array** modified to enable additional detectors in 5-3 configuration **2nd detector array** modified to enable additional detectors in 5-3 configuration	**1st detector array** same as BD FACSCanto II 4-2 configuration but an additional detector is enabled **2nd detector array** same as BD FACSCanto II 4-2 configuration but an additional detector is enabled	**1st detector array** same as BD FACSCanto II 4-2 configuration **2nd detector array** same as BD FACSCanto II 4-2 configuration	**1st detector array** similar to BD FACSCanto 4-2 configuration with minor filter modification. **2nd detector array** similar to BD FACSCanto II 4-2 configuration, with minor filter modification. An additional detector is enabled.
Electronics	Electronics boards containing acquisition electronics components	Electronics board with improved preamplifier circuitry.	Same as BD FACSCanto II 4-2 configuration.	Same as BD FACSCanto II 4-2 configuration.	Similar to BD FACSCanto 4-2 with modifications to the pre-amplifier circuitry.

Feature/ Attribute	BD FACSCanto (4-2): Predicate Device	BD FACSCanto II (4-2): Reference Device	BD FACSCanto II (5-3)	BD FACSCanto II (4-2-2)	BD FACSCanto (4-3-3)
Fluidics	Consists of a pinch valve assembly which controls the flow of sample, saline, and waste fluids. Includes a separate wet cart assembly.	Consists of a block that duplicates FACSCanto fluidic scheme. Use of manifold improves reliability and ease of serviceability.	Same as BD FACSCanto II 4-2 configuration.	Same as BD FACSCanto II 4-2 configuration.	Same as BD FACSCanto II 4-2 configuration.
Fluidics Cart	Original FACSCanto design with FACSFlow™ sheath fluid cubitainer	BD FACSCanto fluidics cart with the incorporation of a manifold assembly and improved chemical compatibility of valve material.	Same as BD FACSCanto II 4-2 configuration.	Same as BD FACSCanto II 4-2 configuration.	Same as BD FACSCanto II 4-2 configuration.
Sample Introduction	Original FACSCanto Sample injection tube (SIT) design	SIT with modified tube guide, sensor, and probe tip	Same as BD FACSCanto II 4-2 configuration.	Same as BD FACSCanto II 4-2 configuration.	Same as BD FACSCanto 4-2
Automated Sample Presentation	BD FACSLoader	BD FACSLoader with updated motor, pneumatic actuation, and sliding access doors	Same as BD FACSCanto II 4-2 configuration.	Same as BD FACSCanto II 4-2 configuration.	Same as BD FACSCanto 4-2
Software	BD FACSCanto clinical software v1.0 or higher BD FACSDiva software v4.0 or higher	BD FACSCanto clinical software v2.1 or higher (currently v3.0) BD FACSDiva software v5.0.1 or higher	Same as BD FACSCanto II 4-2 configuration (currently v3.0).	Same as BD FACSCanto II 4-2 configuration (currently v3.0).	BD FACSCanto clinical software v2.4 or higher (currently v3.0) BD FACSDiva software v7.0 or higher.
Instrument Setup and Quality Control	Automated setup using BD FACSCanto clinical software and BD FACS 7-color setup beads	Same	Same	Same	Same
Sample Preparation	Manual pipetting for the lyse/wash or lyse/no-wash methods, or automated with the BD FACS Sample Prep Assistant (SPA) for the lyse/no-wash method	Same	Same	Same	Same
Sample Type*	Assay-dependent	Same	Same	Same	Same

*Sample Types are assay-dependent; refer to FDA-cleared assays for designated sample types. For use with Multitest 6-color TBNK and IMK kit, whole blood is the indicated sample type in the assay's IFU.

5.9 Substantial Equivalence

Performance of the different configurations of the BD FACSCanto and BD FACSCanto II is equivalent. All instruments have similar intended uses and similar operating principles; any differences in technological characteristics are accompanied by information that demonstrates the devices are as safe and effective as the predicate device configuration. Therefore, these devices are substantially equivalent to the predicate, the BD FACSCanto 4-2 flow cytometry system.

5.10 Performance Data

Table 5-4: Performance Summary

Study	Study Design	Results
Accuracy/Method Comparison	Based on *Method Comparison and Bias Estimation Using Patient Samples*, CLSI document EP9-A2.	The BD FACSCanto II system 4-2-2 and 5-3 configurations and BD FACSCanto system 4-3-3 configuration demonstrated equivalent performance to the predicate for the BD Multitest™ IMK Kit (4-color) and BD Multitest™ 6-color TBNK (with Trucount™) assays.
Precision	Based on *Evaluation of Precision Performance of Clinical Chemistry Devices*, CLSI document EP5-A2.	Assay dependent. The BD FACSCanto II system 4-2-2 and 5-3 configurations and BD FACSCanto system 4-3-3 configuration demonstrated equivalent performance to the predicate for the BD Multitest IMK Kit (4-color) and BD Multitest 6-color TBNK (with Trucount) assays.
Linearity	Based on *Evaluation of the Linearity of Quantitative Measurement Approaches: A Statistical Approach*, CLSI document EP6-A.	Assay- dependent. The BD FACSCanto II system 4-2-2 and 5-3 configurations and BD FACSCanto system 4-3-3 configuration demonstrated equivalent performance to the predicate for the BD Multitest IMK Kit (4-color) and BD Multitest 6-color TBNK (with Trucount) assays.
Carryover	Three samples with a high White Blood Cell concentration were acquired, followed by three low WBC concentration samples. Carryover Calculation: 100% * [(L1-L3) / (H3-L3)]	The mean carryover measured from manual acquisition and the mean carryover from Loader acquisition both met the acceptance criteria described.

5.11 Conclusion

The BD FACSCanto™ II flow cytometers (4-2-2 and 5-3 configurations) and BD FACSCanto™ flow cytometer (4-3-3 configuration) demonstrate substantial equivalence to the predicate device BD FACSCanto™ system 4-2 configuration.